UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION and

THE PEOPLE OF THE STATE OF NEW YORK, by LETITIA JAMES, Attorney General of the State of New York,

Plaintiffs,

v.

QUINCY BIOSCIENCE HOLDING COMPANY, INC., a corporation;

QUINCY BIOSCIENCE, LLC, a limited liability company;

PREVAGEN, INC., a corporation d/b/a/ SUGAR RIVER SUPPLEMENTS;

QUINCY BIOSCIENCE MANUFACTURING, LLC, a limited liability company; and

MARK UNDERWOOD, individually and as an officer of QUINCY BIOSCIENCE HOLDING COMPANY, INC., QUINCY BIOSCIENCE, LLC, and PREVAGEN, INC.,

Defendants.

Case No. 1:17-cv-00124-LLS

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

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PRELIMINARY STATEMENT

Defendants' motion for summary judgment is based in most part on their erroneous contention that requiring a well-designed, randomized, well-controlled, double-blinded human clinical trial ("RCT") to substantiate their advertising claims would go beyond the FTC Act and the FTC's Dietary Supplements: An Advertising Guide for Industry ("FTC Guidance"). But this argument is wholly undercut by the fact that FTC Act case law requires competent and reliable evidence to substantiate Defendants' claims. The relevant law, as well as FTC Guidance, make abundantly clear that "competent and reliable scientific evidence" is defined as the type of evidence an expert in the relevant field would require to support those claims.

It is undisputed that Defendants made, and continue to make, claims that Prevagen: (1) improves memory, (2) improves memory within 90 days, (3) reduces memory problems associated with aging, and (4) provides other cognitive benefits, including healthy brain function, a sharper mind, and clearer thinking (collectively "Challenged Health Efficacy Claims"). Plaintiffs will present an expert in the relevant scientific fields – memory, cognition, and clinical trials – and she will testify that in order to substantiate these claims, one would need a well-conducted RCT that yields statistically significant and clinically meaningful results. Defendants do have a flawed RCT, the Madison Memory Study, but that RCT did not demonstrate that Prevagen improved memory or cognition.

Defendants' claims go a step further and tout to consumers that Prevagen is "clinically shown" to: (1) improve memory, (2) improve memory within 90 days, (3) reduce memory problems associated with aging, and (4) provide other cognitive benefits, including healthy brain function, a sharper mind, and clearer thinking (collectively "Challenged Establishment Claims"). The vast majority of Defendants' ads referred specifically to the Madison Memory Study. As

such, the net impression Defendants conveyed to consumers was that their memory and cognitive function claims were supported by an RCT.

Defendants seek to flout relevant case law by insisting that the FTC Guidance does not mean what it says. They cherry pick isolated phrases from the FTC Guidance while ignoring its overall context and clear directive that, for example, the appropriate level of substantiation is based on what experts in the relevant field would require, the appropriate type of evidence needed depends on the advertising claim that is conveyed to consumers, and marketers must possess the level of support they claim to have in ads. As the case law abundantly demonstrates, experts in the relevant fields often require an RCT, including for a dietary supplement. Given this legal precedent, Plaintiffs, by contending that an RCT is required to substantiate the Challenged Health Efficacy Claims and the Challenged Establishment Claims (collectively "Challenged Claims"), have not imposed a new, "heightened," or "unpublished" standard on Defendants that would violate the Due Process Clause of the Constitution.

In what can only be described as a last-ditch effort to feign ignorance about the clear requirement of an RCT for Defendants' claims, Defendants point to the FDA's Dietary Supplement Health and Education Act of 1994 ("DSHEA"), a statute enforced by the FDA that is entirely irrelevant to the instant action. As this Circuit has noted, FDA has a different regulatory scheme, and its requirements and regulations are inapplicable to an FTC Act case. In any case, DSHEA does not prohibit an RCT from being the appropriate substantiation, and FDA's guidance, even after DSHEA, is consistent with FTC law and guidance on health claim substantiation. DSHEA thus offers Defendants no safe harbor.

Defendants' assertion that Plaintiffs have applied an unprecedented substantiation standard is simply their effort to distance themselves from the telling admission they made at the

November 2021 status conference – that "what we have here are two sides of experts who disagree with each other about science, about the science at issue in this case." (Nov. 12, 2021 Hr'g Tr. at 8:10-12.) Plaintiffs' expert has reached the well-supported conclusion that experts in the relevant fields would require an RCT, and that the RCT conducted by Defendants does not support their advertising claims. Defendants' purported experts disagree. While Defendants' motion for summary judgment obfuscates the relevant legal standard that applies in this case, there is no question that, as they conceded at the November 2021 status conference, "the only thing that's been proven here is that these scientists disagree with each other." (Nov. 12, 2021 Hr'g Tr. at 9:22-23.)

Defendants also offer non-RCT research in support of their claims – studies in laboratories, dogs, rats, and humans – that does not substantiate their claims regarding Prevagen, and therefore precludes summary judgment in their favor. These studies purport to explore the effects of Prevagen's active ingredient, apoaequorin. Not only are they insufficient to support the Challenged Claims because they are not RCTs, but these studies, taken as a whole, refute Defendants' claims. Defendants conducted an *in vitro* study that indicates that apoaequorin is rapidly digested to amino acids in the stomach and can therefore have no therapeutic effect, and the dog and rat studies show that apoaequorin, when orally administered – as Prevagen is – does not survive digestion long enough to have an effect on the brain. Defendants plan to offer purported experts who disagree, but they should be precluded from testifying. And even if the Court allows them to testify, they would, at best, merely offer a dispute of fact.

Defendants' other arguments also fail to support their motion for summary judgment. Contrary to Defendants' assertion, Plaintiffs have not failed to offer evidence that the challenged claims are likely to mislead consumers. Defendants ignore longstanding case law providing that

false or unsubstantiated claims are deceptive as a matter of law. Plaintiffs thus can demonstrate that Defendants' claims are "likely to mislead" by establishing through the testimony of their expert witnesses that Defendants' proffered substantiation is inadequate.

Defendants also inaccurately argue that Plaintiffs are not entitled to injunctive relief because their current advertising no longer makes the Challenged Claims. Defendants are wrong on both the law and the facts. Defendants argue that, because all of their current ads purportedly contain qualifying language required by a settlement agreement in the matter of *Collins v. Quincy Bioscience, LLC* (the "Collins Qualifier" or "Qualifier"), Plaintiffs cannot show that any Defendant "is violating" or "is about to violate" the FTC Act. However, Defendants do continue to disseminate advertising without the Collins Qualifier. Moreover, advertisements with the Qualifier also violate the law because the Qualifier: (1) is insufficiently prominent in Defendants' ads; and (2) references improper and fatally flawed subgroup analysis from the Madison Memory Study. Even if Defendants had discontinued their objectionable ads, an injunction would still be proper as the case law, including the cases relied on by Defendants, demonstrates. To the extent that Defendants continue to contest the net impression of their current advertisements, that – at most – presents an issue of material fact that precludes summary judgment.

Defendants also incorrectly argue that this Court should not grant injunctive relief to the extent that Defendants are complying with the *Collins* settlement, claiming prejudice. This, too, is wrong. A private class action settlement provides no basis for barring relief in this public enforcement action—as the very case on which Defendants rely makes clear—because this action implicates the public's interest and the remedies sought are broader than those sought in a private class action. Moreover, Defendants' claims of prejudice fall flat because Plaintiffs

consistently have made clear that Defendants' advertising is deceptive even if it includes the Collins Qualifier.

Additionally, Defendants' theory that Section 13(b) of the FTC Act prohibits the FTC from seeking a permanent injunction unless it first seeks a temporary restraining order or a preliminary injunction has no legal support. Instead, every court to consider this issue has rejected Defendants' interpretation of Section 13(b) as requiring the FTC to seek preliminary relief before it can seek permanent relief.

Finally, Defendants are simply incorrect that the NYAG's claims are preempted and that the NYAG is not entitled to restitution. Defendants' own authority makes both points abundantly clear. DSHEA does not apply to Defendants' advertising claims and the NYAG can seek restitution for anyone injured since the end of the class period, July 21, 2020.

LEGAL STANDARD FOR SUMMARY JUDGMENT

"The Court shall grant summary judgment if the movant shows," based upon the admissible evidence, "that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *Chanel, Inc. v. WGACA, LLC*, No. 18-cv-2253 (LLS), 2022 U.S. Dist. LEXIS 55880, at *11 (S.D.N.Y. Mar. 28, 2022) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986)) (quotation marks omitted). A fact is material if, based on the substantive law, it "might affect the outcome of the suit under the governing law," and it is genuinely in dispute "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Chanel, Inc.*, 2022 U.S. Dist. LEXIS 55880, at *11 (citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986) and *Baez v. JetBlue Airways Corp.*, 793 F.3d 269, 274 (2d Cir. 2015)).

Defendants as the moving party bear the initial burden of demonstrating the absence of a genuine issue of material fact, a burden which they have not met. *Chanel, Inc.*, 2022 U.S. Dist.

LEXIS 55880, at *11. District courts are "not 'to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial.'" *Id*. at *11-12 (citing *Cioffi v. Averill Park Cent. Sch. Dist. Bd. of Ed*., 444 F. 3d 158, 162 (2d Cir. 2006)). The district court "must construe all the evidence in the light most favorable to the nonmoving party . . . and draw all inferences and resolve all ambiguities in that party's favor" and against the motion. *Id.* at *12 (citing *Cartier, Inc. v. Sardell Jewelry, Inc.*, 294 F. App'x 615, 617 (2d Cir. 2008)).

In this case, given the number of outstanding genuine issues of material facts in dispute, summary judgment is wholly inappropriate.

ARGUMENT

I. PLAINTIFFS HAVE APPLIED THE SUBSTANTIATION STANDARDS CONSISTENT WITH FTC LAW AND THE FTC GUIDANCE

Defendants contend that an RCT cannot be required to substantiate claims for a dietary supplement because such a requirement would go beyond the FTC Act and the FTC Guidance. (Defs.' Br. at 1-2, 19.) However, Defendants overlook the fact that they advertised to consumers that Prevagen's benefits were supported by an RCT, mischaracterize the FTC's competent and reliable scientific evidence standard, disregard the opinion of Plaintiffs' expert that Defendants' claims must be supported by an RCT, and fail to acknowledge the many cases finding that an RCT was the appropriate type of substantiation even for a dietary supplement.

A. Because Defendants Advertised That Their Claims Were Supported by an RCT, an RCT is Required as Substantiation

Defendants' argument that any requirement of an RCT contradicts the FTC Act[1] and the FTC Guidance amounts to nothing more than an attempt to obscure an undisputed fact –

[1] Case law under the FTC Act is given great weight in construing the New York consumer protection statutes at issue in this case. *See In re People v. Applied Card Sys., Inc.*, 27 A.D.3d

Defendants advertised for years (and still do) that their claims were supported by evidence from an RCT. (*See*, *e.g.*, Compl. Exs. A, C; Defs.' SOF ¶¶ 28, 31, 52.) In advertising, Defendants expressly connected the purported results of the Madison Memory Study, an RCT, to the Challenged Claims. For example, in addition to telling consumers that Prevagen was "clinically shown to improve memory," Defendants advertised that:

> Prevagen Improves Memory*
>
> Prevagen has been clinically shown to help with mild memory loss associated with aging.*
>
> …
>
> Unique Ingredient in Prevagen
> Prevagen contains apoaequorin, which was originally discovered in jellyfish. Apoaequorin is patented by Quincy Bioscience for use in a variety of products to support cognitive function.* In a computer-assessed, double-blinded, placebo-controlled clinical study, Prevagen improved certain aspects of cognitive function over a 90 day period.*

(Ducklow Decl. Attachment 1, Prevagen.com at FTC-0000139.0003-04.) Further, as admitted by Defendants, product packaging stated that "Prevagen Improves Memory," "Prevagen is clinically shown to help with mild memory loss associated with aging[,]" and that "[i]n a computer-assessed double-blinded, placebo-controlled clinical study, Prevagen improved certain aspects of cognitive function over a 90 day period." (Olson Decl. ¶¶ 28-30, Ex. E at QUI-FTCNY-00013352); *see also* Ducklow Decl. Attachment 10 (stating in a TV ad that "[i]n a computer assessed, double-blinded, placebo controlled study, Prevagen improved recall tasks in subjects" and showing a bar chart of the purported improvement over 90 days).) The net

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104, 105 (3d Dep't 2005), *aff'd on other grounds*, 11 N.Y.3d 105 (2008) (explicitly "recognizing that the interpretations of the Federal Trade Commission Act (*see* 15 U.S.C. § 45 et seq.) are useful in determining the aforementioned violations under both the Executive Law and General Business Law"); *State v. Feldman*, 210 F. Supp. 2d 294, 302 (S.D.N.Y. 2002); *Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank*, 85 N.Y.2d 20, 26 (1995); *State v. Colorado State Christian Coll. of Church of Inner Power, Inc.*, 76 Misc. 2d 50, 54 (1973).

impression of these advertisements clearly communicated to consumers that Prevagen's benefits for cognitive function were supported by clinical evidence, specifically an RCT.[2]

Claims that identify a specific type of substantiation, like those alleged in Count II of the Complaint, are "establishment claims," and Defendants must have had the type of evidence claimed. (Compl. ¶ 39; *FTC v. Roca Labs, Inc.*, 345 F. Supp. 3d 1375, 1381, 1388 (M.D. Fl. 2018) (noting that an establishment claim is required to have the level of proof claimed in the ad); *FTC v. Coorga Nutraceuticals*, 201 F. Supp. 3d 1300, 1309 (D. Wyo. 2016) ("If an establishment claim 'states a specific type of substantiation,' the 'advertiser must possess the specific substantiation claimed.'" (quoting *Removatron Corp. v. FTC*, 884 F.2d 1489, 1492 n.3 (1st Cir. 1989)); *FTC v. Wellness Support Network*, No. 10-cv-04879-JCS, 2014 WL 644749, at *16 (N.D. Cal. Feb. 19, 2014) (finding that "for establishment claims advertisers must have the level of substantiation referenced in the claim itself" and applying this standard to advertising claims that referenced clinical and scientific studies); *FTC v. Direct Mktg. Concepts, Inc.*, 569 F. Supp. 2d 285, 298-99 (D. Mass. 2008). The FTC Guidance reinforces this standard for an establishment claim, stating that "[i]f an advertiser asserts that it has a certain level of support for an advertised claim, it must be able to demonstrate that the assertion is accurate. Therefore, as a starting point, advertisers must have the level of support that they claim, expressly or by implication, to have." (Graham Decl. Ex. F, FTC Guidance at QUI-FTCNY-00189212.)

Under FTC law, for the establishment claims alleged in the Complaint, Defendants are required to have the level of evidence touted repeatedly in their own ads – evidence from an RCT – to support the challenged claims. *See Wellness Support Network*, 2014 WL 644749, at

[2] If Defendants were to contend that they did not make any establishment claims in their ads, these would be material facts in dispute and summary judgment would be inappropriate.

*16 (finding unsupported establishment claims to be false). Defendants' position that they could advertise that an RCT is evidence of Prevagen's efficacy without being required to have an adequate RCT contradicts FTC law and common sense.

B. For the Challenged Health Efficacy Claims, Plaintiffs Have Applied the Competent and Reliable Scientific Evidence Standard Consistent with FTC Law

Defendants' ads tout the efficacy of Prevagen by claiming that it improves memory and provides other cognitive benefits. As compared to an establishment claim, "[a]n efficacy claim suggests that a product successfully performs the advertised function or yields the advertised benefit, but includes no suggestion of scientific proof of the product's effectiveness." *POM Wonderful v. FTC*, 777 F.3d 478, 490 (D.C. Cir. 2015). "If an ad conveys an efficacy claim, the advertiser must possess a reasonable basis for the claim." *Id.* (quotation marks omitted). If an advertiser lacks a reasonable basis to substantiate a claim at the time of dissemination, the advertisement would be deceptive under the FTC Act.[3] *COORGA Nutraceuticals*, 201 F. Supp. 3d at 1309. What constitutes a reasonable basis can depend on multiple factors, including the type of claim and product, consequences of a false claim, benefits of a truthful claim, ease of developing substantiation for the claim, and the amount of substantiation experts in the field would consider reasonable. *POM Wonderful*, 777 F.3d at 490-91. For a health efficacy claim, courts have interpreted the reasonable basis requirement to mean competent and reliable scientific evidence. *NPB Adver., Inc.*, 218 F. Supp. 3d at 1358; *FTC v. Nat'l Urological Grp.*, 645 F. Supp. 2d 1167, 1202 (N.D. Ga. 2008); *FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 961 (N.D. Ill. 2008). "[T]he 'competent and reliable scientific evidence' standard is one which has been

[3] In addition to the showing that there was no reasonable basis, Plaintiffs would have to show that Defendants made the challenged representations, expressly or impliedly, and that the claims were material. *FTC v. NPB Adver., Inc.*, 218 F. Supp. 3d 1352, 1358 (M.D. Fla. 2016).

developed over many years by agency enforcement precedent and guidance from the FTC." *Direct Mktg. Concepts, Inc. v. FTC*, 581 F. Supp. 2d 115, 118 (D. Mass. 2008).

To determine what constitutes competent and reliable scientific evidence, courts regularly look to experts in the relevant field. *See, e.g.*, *Daniel Chapter One v. FTC*, 405 F. App'x 505, 506 (D.C. Cir. 2010); *COORGA Nutraceuticals*, 201 F. Supp. 3d at 1309; *FTC v. Alcoholism Cure Corp.*, No. 3:10-cv-266-J-34JTB, 2011 WL 13137951, at *27 (M.D. Fla. Sept. 16, 2011) ("The Court can look to what experts in the relevant area of study would consider to be adequate in determining the amount and type of evidence that is sufficient for scientific validation of the advertisement's claims." (quotation marks omitted)); *Nat'l Urological Grp.*, 645 F. Supp. 2d at 1186. This standard is flexible because it "is context specific and permits different variations . . . depending on what pertinent professionals would require for the particular claim made." *Nat'l Urological Grp.*, 645 F. Supp. 2d at 1186. This approach also is set forth in the FTC Guidance, which provides that a "guiding principle for determining the amount and type of evidence that will be sufficient is what experts in the relevant area of study would generally consider to be adequate." (Graham Decl. Ex. F, FTC Guidance at QUI-FTCNY-00189213.) In this case, Plaintiffs' expert, Mary Sano, Ph.D., relied on her experience in the fields of memory, cognitive impairment, neurosciences of aging and dementia, and clinical trials, and applied the scientific standards that are widely used by experts in these fields. (Plaintiffs' Statement of Additional Material Facts in Dispute ("Pls.' SOF") ¶ 4.) Dr. Sano determined that evidence from an RCT is required to establish the efficacy of Prevagen for memory and other cognitive benefits in humans. (*Id.* ¶ 1.)

Although Defendants concede that the competent and reliable scientific evidence standard is based on what experts in the relevant fields would require, they contend that an RCT

cannot be required, despite the opinion from Dr. Sano, and rely on three civil contempt cases – *Basic Rsch. v. FTC*, No. 2:09-cv-0779, 2014 WL 12596497 (D. Utah Nov. 25, 2014), *FTC v. Garden of Life*, 516 F. App'x 852 (11th Cir. 2013), and *United States v. Bayer Corp.*, No. 07-01, 2015 WL 5822595 (D.N.J. Sept. 24, 2015). (Defs.' Br. at 1-3, 21-23.) However, those cases are inapposite because the courts were deciding whether the FTC had established by clear and convincing evidence that defendants violated a specific provision of a prior court order that did not expressly mention RCTs. *Garden of Life*, 516 F. App'x at 854; *Bayer*, 2015 WL 5822595, at *1; *Basic Rsch.*, 2014 WL 12596497, at *1. Here, the Court is not being asked to interpret a prior order. Rather, the determination of what constitutes competent and reliable scientific evidence for the claims at issue, and whether Defendants possessed such evidence, are disputed questions of fact. In *Roca Labs*, *Inc.*, the court reinforced this distinction, noting that *Bayer* was "inapposite both procedurally and factually" because the FTC was "not challenging a consent decree such that it carries a legal burden to establish a violation by clear and convincing evidence" and "[was] not precluded from requiring RCTs or challenging claims for lack of an RCT." 345 F. Supp. 3d at 1387.

Furthermore, Defendants' position is undercut by the fact that courts have regularly applied the competent and reliable scientific evidence standard and concluded that an RCT was required to substantiate claims based on expert evidence, including for dietary supplements. *See*, *e.g.*, *POM Wonderful*, 777 F.3d at 505; *Daniel Chapter One*, 405 F. App'x at 506 (noting that there was nothing "unreasonable about the specific type of basis required by the Commission, namely, 'competent and reliable scientific evidence' including clinical trials with human subjects"); *Roca Labs, Inc.*, 345 F. Supp. 3d at 1381, 1387-89; *NPB Adver., Inc.*, 218 F. Supp. 3d at 1359; *COORGA Nutraceuticals*, 201 F. Supp. 3d at 1309 (finding that an RCT is the requisite

level of substantiation); *Alcoholism Cure Corp.*, 2011 WL 13137951, at *39 (noting that many courts have "embrac[ed] the placebo-controlled, double-blind clinical study as the most basic and fundamental requirement for scientific validity and reliability to support health-related claims (including dietary supplements)"); *Nat'l Urological Grp., Inc.*, 645 F. Supp. 2d at 1202; *Direct Mktg. Concepts, Inc.*, 569 F. Supp. 2d at 303-04 (stating that it is "well-accepted that double-blind, placebo-controlled studies are necessary to substantiate health-related efficacy claims"); *FTC v. Braswell*, No. CV 03-3700, 2005 WL 4227194, at *10 (C.D. Cal. Sept. 27, 2005) (listing cases where "courts . . . have found or upheld that double-blind, placebo controlled studies are required to provide adequate substantiation for various efficacy claims, including claims for dietary supplements"). The Court should reject Defendants' argument that an RCT is inconsistent with the competent and reliable scientific evidence standard.

C. For the Challenged Health Efficacy Claims, Plaintiffs Have Applied the Competent and Reliable Scientific Evidence Standard Consistent with the FTC Guidance

Defendants also contend that requiring an RCT would be inconsistent with the FTC Guidance, pointing to statements that there is "no set protocol for how to conduct research" or "no fixed formula for the number or type of studies or for specific parameters like sample size and study duration." (Defs.' Br. at 19, 27.) As pointed out above, however, Plaintiffs' position regarding the need for an RCT to substantiate the Challenged Establishment and Health Efficacy Claims is completely consistent with the FTC Guidance. (Graham Decl. Ex. F, FTC Guidance at QUI-FTCNY-00189212-13.) Defendants' argument is meritless because it relies on an incomplete reading of the FTC Guidance that singles out a few sentences while ignoring the surrounding context.

The FTC Guidance "illustrat[es] how principles of ad interpretation and substantiation apply in the context of dietary supplement advertising," but does not specifically cover every

imaginable situation for a large industry selling innumerable products with different claims. (*Id.* at QUI-FTCNY-00189206.) The absence of a set protocol or a fixed formula does not mean the FTC Guidance has no principles on how evidence should be evaluated. For example, after the FTC Guidance says there is no set protocol, the very next sentence states that there are "some principles generally accepted in the scientific community to enhance the validity of test results[,]" including that "a study that is carefully controlled, with blinding of subjects and researchers, is likely to yield more reliable results, "[s]tatistical significance of findings is also important, and "[t]he results should also translate into a meaningful benefit for consumers." (*Id.* at QUI-FTCNY-00189215.) Likewise, directly after stating that there is no fixed formula, the FTC Guidance notes that "[t]here are, however, a number of considerations to guide an advertiser in assessing the adequacy of the scientific support for a specific advertising claim," including whether the ad cites a specific level of support, the amount, type, quality, and relevance of the evidence, and how to consider the totality of the evidence. (*Id.* at QUI-FTCNY-00189212-21.)

Additionally, the FTC Guidance neither expressly prohibits an RCT from being the appropriate level of evidence for a specific claim nor requires that the various types of evidence be weighed equally. (*Id.* at QUI-FTCNY-00189213, QUI-FTCNY- 00189215.) Statements in the FTC Guidance referring to a "totality of the evidence," and that "studies cannot be evaluated in isolation," have been taken out of context and do not mean that an RCT is not the appropriate type of evidence. (Defs.' Br. at 2, 19.) To the contrary, the FTC Guidance explicitly clarifies in the next sentence that:

> [t]he surrounding context of the scientific evidence is just as important as the internal validity of individual studies. Advertisers should consider all relevant research relating to the claimed benefit of their supplement and should not focus only on research that

supports the effect, while discounting research that does not.

(Graham Decl. Ex. F, FTC Guidance at QUI-FTCNY-00189217.) "The surrounding body of evidence will have a significant impact both *on what type, amount and quality of evidence* is required to substantiate a claim and on how that claim is presented – that is, how carefully the claim is qualified to reflect accurately the strength of the evidence." (*Id.* (emphasis added).) Elsewhere, the FTC Guidance notes that "[a]s a general rule, well-controlled human clinical studies are the most reliable form of evidence" and that advertisers should "look first to the results of the studies with more reliable methodologies." (*Id.* at QUI-FTCNY-00189213, QUI-FTCNY-00189217.) To illustrate a scenario in which RCTs were considered essential, the FTC Guidance includes a hypothetical example about a dietary supplement for which the evidence was determined to be likely inadequate because the non-RCT evidence was methodologically flawed and "human research [was] both feasible and the *accepted approach* in the field." (*Id.* at QUI-FTCNY-00189213-14 (emphasis added).)

Furthermore, courts have found the FTC Guidance to be consistent with FTC case law requiring an RCT. In *Daniel Chapter One*, the court found that the FTC Guidance "gave notice that a reasonable basis for a claim concerning a dietary supplement consists of scientific evidence, including clinical trials." 405 F. App'x at 506 (stating that the FTC "generally relies upon experts for evidence of the 'accepted norms in the relevant field,' and the expert testimony. . . in the present case supports the type of substantiation it required of [the advertiser]" (quoting the FTC Guidance)). Additionally, *Daniel Chapter One* found nothing "unreasonable about the specific type of basis required by the Commission, namely, 'competent and reliable scientific evidence' including clinical trials with human subjects." *Id.* Likewise, *COORGA Nutraceuticals* noted that the FTC Guidance was consistent with FTC law, stating that "[w]hile it is true, as

Defendants point out, that the FTC's advertising guide suggests there may be other scientific evidence that could be sufficient and that a double-blind study is not *necessarily* required in all instances, the FTC has established that a human clinical trial is required for the claims made by Defendants that its dietary supplements reverse or prevent the graying of human hair." 201 F. Supp. 3d at 1310 (emphasis in original). The *COORGA Nutraceuticals* court noted that the Guidance indicated the need to have competent and reliable scientific evidence and that "'[a] guiding principle for determining the amount and *type of evidence* that will be sufficient is what experts in the relevant area of study would generally consider to be adequate.'" *Id*. at 1309 (quoting the FTC Guidance) (emphasis added); *see also* Defs.' Br. at 19 (conceding that the competent and reliable scientific standard is based on the expertise of professionals in the relevant area).

Defendants take issue with the fact that Plaintiffs' experts did not consider the FTC Guidance, but this misconstrues the role of Plaintiffs' experts and the purpose of the FTC Guidance. The FTC Guidance is intended to assist marketers of dietary supplements, not scientific experts, in understanding how FTC law applies to advertising claims. (Graham Decl. Ex. F, FTC Guidance at QUI-FTCNY-00189204-05.) Comparatively, scientific experts are relying on principles or procedures generally used in their field. Plaintiffs' experts are opining, for example, on "the amount and type of evidence that will be sufficient" to support the claims or on whether the purported substantiation has "been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." (*Id.* at QUI-FTCNY-00189206, QUI-FTCNY-00189212-13.)

D. Plaintiffs' Contention that Defendants' Claims Must be Substantiated By an RCT Does Not Violate Defendants' Due Process Rights

Defendants argue that Plaintiffs, by contending that an RCT is required to substantiate the challenged claims, have imposed a "heightened" and "unpublished" standard on Defendants in violation of the Due Process Clause of the Constitution. As set forth above, however, Plaintiffs followed well-established case law and FTC Guidance in determining the proper level of substantiation for both the challenged establishment and efficacy claims. *See supra* Section I.A-B. Furthermore, in *Daniel Chapter One*, the court rejected Defendants' specific argument that requiring an RCT constitutes a heightened substantiation standard, noting that such a level of substantiation is consistent with the FTC Guidance. 405 F. App'x at 506.

In making their Due Process argument, Defendants incorrectly assert that Plaintiffs' experts considered only the Madison Memory Study in determining whether Defendants' claims were adequately supported. (Defs.' Br. at 31.) In fact, Plaintiffs' expert, Dr. Sano, reviewed the other purported substantiation, including human and animal studies, and found that none of those additional materials supported the claims at issue. (Pls.' SOF ¶¶ 47-49, 51-56.) Defendants' Due Process argument therefore is without basis in law or fact.

Defendants' assertion that Plaintiffs have applied a higher standard, beyond the FTC Act or the FTC Guidance, is simply an effort to avoid what Defendants previously told the Court – that "what we have here are two sides of experts who disagree with each other about science, about the science at issue in this case." (Nov. 12, 2021 Hr'g Tr. at 8:10-12.) Indeed, both parties intend to offer competing evidence from experts on what constitutes competent and reliable scientific evidence and whether Defendants' establishment and efficacy claims are adequately supported. (*See infra* Sections II-IV; Pls.' SOF ¶¶ 1-56.) Therefore, these disputed material facts must be resolved at trial, not at summary judgment. *Nat'l Urological Grp.*, 645 F. Supp.

2d. at 1190 (stating that "what constitutes competent and reliable scientific evidence . . . is a question of fact for expert interpretation"); *Griffin v. Sheeran*, 351 F. Supp. 3d 492, 497 (S.D.N.Y. 2019) (denying summary judgment because experts disagree on a factual issue); *R.F.M.A.S. v. So*, 619 F. Supp. 2d 39, 81 n.21 (S.D.N.Y. 2009) (competing expert opinions on a question of fact, either of which the jury could credit, precludes summary judgment).

E. DSHEA Is Inapplicable to a Case Brought Under the FTC Act

Defendants mistakenly equate the requirement of an RCT to support the claims under FTC law with FDA's regulatory scheme for drugs based on DSHEA. (Defs.' Br. at 17.) First, DSHEA, which is enforced by the FDA, is inapplicable because this case was brought pursuant to the FTC Act and parallel New York law. Courts have found that FDA administers a different regulatory scheme that is inapplicable to the FTC Act. *See Bristol-Myers Co. v. FTC*, 738 F.2d 554, 559 (2d Cir. 1984); *see also Thompson Medical Co. v. FTC*, 791 F.2d 189, 193 (D.C. Cir. 1986) (stating that *Bristol-Myers* made it quite clear that FDA requirements and regulations were a different regulatory scheme and did not govern an FTC case); *FTC v. Lunada Biomedical*, No. CV-15-3380-MWF, 2015 WL 12911515, *4-5 (C.D. Cal. Sept. 23, 2015) (noting that FDA requirements and regulations did not apply even when the product at issue was a dietary supplement); *Wellness Support Network*, 2014 WL 644749, at *10 (rejecting as irrelevant the argument that the standard that applies to claims under the FTC Act must take into account FDA regulations).[4]

[4] Similarly, FDA guidance cited by Defendants, such as the Small Entity Compliance Guide on Structure/Function Claims, would also be inapplicable to this case.

Furthermore, DSHEA does not prohibit an RCT from being the appropriate substantiation in this case.[5] Defendants concede that "DSHEA does not elaborate on what is required for a claim to be considered 'truthful and not misleading.'" (Defs.' Br. 18.) Likewise, the FTC Guidance notes that DSHEA "does not directly apply to advertising." (Graham Decl. Ex. F, FTC Guidance at QUI-FTCNY-00189204, 00189226 (stating also that a disclaimer authorized under DSHEA may not cure an otherwise deceptive ad).) Contrary to Defendants' assertions that DSHEA mandates a lower substantiation standard for dietary supplements, FDA noted that it "intend[ed] to apply a standard for the substantiation of dietary supplement claims that is consistent with the FTC approach," and therefore a claim is required to have adequate substantiation and not be misleading. (Ducklow Decl. Attachment 9, Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r) (6) of the Federal Food, Drug, and Cosmetic Act at 5 (noting that "DSHEA did not define 'substantiation'").) FDA further states that, like the FTC Guidance and FTC case law, the type of evidence sufficient to substantiate a claim depends on "what experts in the relevant area of study would consider to be competent and reliable. Competent and reliable scientific evidence adequate to substantiate a claim would consist of information derived primarily from human studies." (*Id.* at 12.) For example, intervention studies, specifically "[r]andomized, double blind, parallel group, placebo-controlled trials offer the greatest assessment of a relationship between a dietary supplement and an outcome." (*Id.* at 12-13.) Comparatively, *in vitro* and animal studies are not sufficient to substantiate a claim while observational studies "have a more limited ability than intervention

[5] Even if it were relevant to an FTC Act case, DSHEA applies only to labeling, not other types of advertising like radio or television. (Ducklow Decl. Attachment 9, Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r) (6) of the Federal Food, Drug, and Cosmetic Act at 3-4.)

studies to distinguish relationships between a substance and the outcomes being evaluated and cannot provide causal evidence." (*Id.* at 12, 14, 16 (providing an example that a claim supported by *in vitro* tests would not have adequate substantiation because "[c]orroborating evidence from some human studies would likely be needed to determine if the in vitro findings reflect the outcomes of the product when consumed by humans").)

Defendants' attempt to impose DSHEA into this case is without merit because it is both inapplicable to a case under the FTC Act and does not prohibit an RCT from being the appropriate substantiation for the Challenged Claims. The Court should instead apply the law under which Plaintiffs' claims were alleged – the FTC Act and parallel New York law.

II. GENUINE ISSUES OF MATERIAL FACT EXIST AS TO WHETHER AN RCT IS NEEDED TO SUBSTANTIATE THE CHALLENGED CLAIMS

The parties' experts disagree on the standard of evidence Defendants are required to have to substantiate the Challenged Claims, and, therefore, summary judgment in favor of Defendants is unwarranted. (Pls.' SOF ¶¶ 1-15.) Plaintiffs' expert opines that experts in her respective fields of memory, cognition, neurosciences of aging and dementia, and clinical trials would require competent and reliable scientific evidence in the form of a well-designed, randomized, well-controlled, double-blinded clinical trial ("RCT") to support the Challenged Claims. (*Id.* ¶ 1.) [redacted] (*Id.* ¶ 2.) "[W]hat constitutes competent and reliable scientific evidence in this case is a question of fact for expert interpretation." *Nat'l Urological Grp.*, 645 F. Supp. 2d at 1190. This, and the other numerous disagreements between the parties' experts, illustrate the inappropriateness of summary judgment.

Plaintiffs' expert, Dr. Sano, an expert in the fields of (1) memory; (2) cognition; (3) neurosciences of aging and dementia; and (4) the design, implementation, and interpretation of

clinical trials, examined Defendants' proffered substantiation. (Pls.' SOF ¶¶ 4-5.) Dr. Sano has opined that establishing the efficacy of an orally-administered product like Prevagen for memory and other cognitive benefits requires competent and reliable scientific evidence in the form of at least one RCT on the actual product, or a substantially similar product, for which the advertising claims are made. (Pls.' SOF ¶ 1.)

In rendering her opinion as to the required form of evidence to substantiate the Challenged Claims, Dr. Sano drew upon her education and experience and applied the scientific standards that are widely used by experts in her fields. (Pls.' SOF ¶ 4.) Her review of Defendants' research was based on a standard of evidence that conforms to research methods accepted in those scientific communities as capable of supporting valid conclusions as to causation. (*Id.* ¶ 5.)

Although Defendants continue to advertise that Prevagen improves memory and cognition and tout that they have an RCT, [redacted] (*Id.* ¶ 2-3.) [redacted].[6] (*Id.* ¶ 2.)

In addition to creating a new, lower evidentiary standard, without defining such a standard, Defendants fault Dr. Sano for not reviewing or considering the FTC Guidance, FDA

[6] Although Prevagen could be described as a dietary supplement in everyday parlance and, for this reason, Plaintiffs described Prevagen as such in their Complaint, whether FDA would classify Prevagen as a "dietary supplement" or a "drug" is irrelevant to the instant action. *See Bristol-Myers Co.*, 738 F.2d at 559. The issue under the FTC Act is whether the claims Defendants made to consumers are supported by competent and reliable scientific evidence. That question can and should be answered under FTC law, which provides for consideration of the opinion of experts in the relevant field, without reference to FDA regulations.

regulations, or any other law or regulation in forming her opinion as to what constitutes competent and reliable scientific evidence. This criticism is misplaced. Plaintiffs did not retain Dr. Sano to provide legal opinions, which would be inappropriate, and it was unnecessary for her to review or consider the FTC Guidance, FDA regulations, or any other law or statute.[7] (Soberats Decl. Ex. A, Sano Aff. Report ¶ 13.)

In sum, the parties' experts disagree as to the requisite level of evidence required for the Challenged Claims. Clearly the question of whether the Defendants were required to have an RCT to substantiate their marketing claims is a disputed issue of material fact that is unripe for summary judgment.

III. GENUINE ISSUES OF MATERIAL FACT EXIST AS TO WHETHER DEFENDANTS' RCT CONSTITUTES COMPETENT AND RELIABLE SCIENTIFIC EVIDENCE FOR THE CHALLENGED CLAIMS

The parties have submitted reports by experts who dispute virtually every aspect of the Madison Memory Study, Defendants' primary human clinical study, including the study's design, implementation, and analysis. (Pls.' SOF ¶¶ 16-46.) These disputed material facts go directly to the determination of whether Defendants possessed competent and reliable scientific evidence or had the clinical evidence they touted in their ads. *See Nat'l Urological Grp.*, 645 F. Supp. 2d. at 1190 (stating that "what constitutes competent and reliable scientific evidence . . . is a question of fact for expert interpretation"). Where experts disagree on a question of fact for the fact finder, summary judgment is inappropriate. *See Griffin*, 351 F. Supp. 3d at 497 (denying summary judgment because experts disagree on a factual issue); *see also R.F.M.A.S.*, 619 F.

[7] The opinions expressed by Defendants' experts constitute inappropriate legal conclusions that are not based on a reliable scientific methodology as required under Rule 702 and *Daubert* and should be excluded. *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579 (1993).

Supp. 2d at 81 n.21 (competing expert opinions on a question of fact, either of which the jury could credit, precludes summary judgment).

A. Genuine Issues of Material Fact as to the Madison Memory Study's Design and Implementation

The parties agree that Defendant Quincy Bioscience, LLC sponsored the Madison Memory Study and conducted the study from 2009 to April 2011. The study was a randomized clinical trial that involved more than 200 adults between the ages of 40 and 95 who took either 10 mg of orally-administered apoaequorin (Prevagen) or a placebo control. (Pls.' SOF ¶ 16; Pls.' Resp. Defs. SOF ¶ 97.) There is little else that the parties agree on regarding the study's design and implementation.

Notably, the parties' experts offer conflicting opinions on various aspects of the Madison Memory Study's design, including: (1) how many participants were enrolled; (2) whether Defendants administered the screening tool, the AD8 Dementia Screening Interview ("AD8"), in a reliable manner; and (3) [redacted]. (Pls.' SOF ¶¶ 17-24.) The parties' experts cannot even agree on whether the Madison Memory Study was double-blinded. (*Id.* ¶¶ 25-26.) The experts' disagreements over these aspects of the study's design relate to the question of whether the Madison Memory Study was well-designed, "using procedures generally accepted in the profession to yield accurate and reliable results." (Graham Decl. Ex. F, FTC Guidance at QUI-FTCNY-00189212.)

More importantly, the parties' experts reach different conclusions about the Madison Memory Study's intended study population. Plaintiffs' experts concluded that the intended study population consisted of the over 200 adults who completed the study (all adults scoring between a zero to eight on the AD8 screener). (Pls. SOF ¶ 27.) Defendants' experts counter that the intended study population only consisted of two overlapping subgroups of 100 participants who

had little to no cognitive impairment (adults scoring between a 0-1 on the AD8, and adults scoring between a 0-2 on the AD8).[8] (*Id.* ¶ 28.) However, nothing in the study's protocol or the study's recruitment materials states, or even suggests, that Defendants intended to just analyze the two overlapping subgroups instead of the entire study population. (*Id.* ¶¶ 27, 30, 31.) There isn't even a passing reference to the AD8 in any of these materials. (*Id.*)

The experts' conflicting opinions on the intended study population are critical because they go the very heart of how to interpret the Madison Memory Study's results, a question not resolvable by summary judgment. Drs. Sano and Janet Wittes, Ph.D. – Plaintiffs' expert in biostatistics, the design and analysis of RCTs, and interpretation of data from RCTs – concur that while an RCT's protocol may list subgroups of participants with the goal of testing the efficacy of the treatment in those subgroups, to make any formal inferences about specific subgroups, one must prespecify those subgroups in the RCT's protocol before the study begins. (*Id.* ¶ 10.) Conclusions about a product's efficacy should not be based on an analysis of subgroups that was not specified in the protocol before the study started. (*Id.*) These subgroup findings, often referred to as *post hoc* subgroup findings, should be confirmed in follow-up research on the target population before they can be relied on as valid evidence of a real effect. (*Id.* ¶ 11.)

It is here that the parties' experts offer conflicting opinions about the implementation of the Madison Memory Study. [redacted]. (*Id.* ¶¶ 29-34.) [redacted]

[8] All participants who are in the AD8 0-1 subgroup are also in the AD8 0-2 subgroup.

[redacted]. (*Id.* ¶¶ 32-34.) Because Plaintiffs' experts maintain that the AD8 0-1 and 0-2 subgroups were not prespecified in the study's protocol or elsewhere before the study started, any analyses of subgroups of the study population would be considered *post hoc* statistical analyses that cannot support conclusions about a product's efficacy. (*Id.* ¶¶ 10-11, 27, 30-31.)

[redacted], and seek to reinvent history by claiming that Defendants decided to focus on the AD8 0-1 and AD8 0-2 subgroups before the Madison Memory Study commenced. (*Id.* ¶¶ 28-29, 32-34; Defs.' SOF ¶¶ 100-103, 107, 113.) In support, they argue that Defendants' target market has always been "healthy, non-demented individuals," which makes results for the AD8 0-1 and 0-2 subgroups the most relevant findings. (Defs.' SOF ¶ 113.)

On the conflicting factual record, it cannot be determined as a matter of law what the Madison Memory Study's intended population was and whether Defendants analyzed the various subgroups before or after the Madison Memory Study was completed. To the extent that the views of Plaintiffs' experts prevail, then any analyses of subgroups of the study population would be considered *post hoc* statistical analyses that according to Plaintiffs' experts cannot support conclusions about Prevagen's efficacy. (Pls.' SOF ¶¶ 10, 11.) Such *post hoc* findings should be confirmed in follow-up research of the target population before they can be relied on as valid evidence of a real effect. (*Id.* ¶ 11.) "[C]redibility of experts is a matter best left in the hands of the trier of fact and is inappropriate for resolution on summary judgment." *Chanel, Inc.*, 2022 U.S. Dist. LEXIS 55880, at *21. It is only when the witnesses are present and subject to cross-examination that their credibility and the weight to be given their testimony can be appraised." *Id.* at 33-34 (citing *Poller v. Columbia Broad. Sys., Inc.*, 368 U.S. 464, 473 (1962)).

B. Genuine Issues of Material Fact as to the Madison Memory Study's Results

Ultimately, whether the Madison Memory Study constitutes competent and reliable scientific evidence turns on whether the results were statistically significant and clinically meaningful. (Pls.' SOF ¶¶ 13-15.) According to Plaintiffs' experts, the main finding of the Madison Memory Study is that there were no statistically significant results between the treatment and control groups on any of the outcome measures for the entire study population, which consisted of over 200 adults, based on a Type I error rate of p less than or equal to 0.05. (*Id.* ¶ 35.) Plaintiffs' experts maintain, and Defendants' experts dispute, that this analysis of the entire study population is the only one contemplated in the protocol, and by scientific convention, should be the only result from which conclusions about efficacy can be drawn. (*Id.* ¶¶ 37-38.) Because there was no statistically significant benefit of treatment over control for any cognitive task in the study population as a whole, the Madison Memory Study does not support the Challenged Claims. (Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 35, 37.)

[redacted] (Pls.' SOF ¶ 36.) Dr. Wei holds steadfast to this view even though Defendants used a Type I error rate of p less than or equal to 0.05 to determine statistical significance in the Madison Memory Study itself, and Plaintiffs' experts are measuring the study's results using the very measure of statistical significance Defendants selected. (Pls.' SOF ¶ 35.) Notwithstanding the fault in Dr. Wei's criticism, the fact remains that the parties' experts cannot even agree on the main finding of Defendants' primary substantiation, thereby rendering summary judgment wholly inappropriate.

In addition, the parties' experts disagree on whether certain so-called "statistically significant" results for the AD8 0-1 and 0-2 subgroups are, in fact, statistically significant. (Pls.'

SOF ¶¶ 39-42.) According to Plaintiffs' experts, any selective findings that Defendants publicly reported as "statistically significant" for the AD8 0-1 and 0-2 subgroups are unreliable because they are based on extensive and statistically flawed *post hoc* mining of the data that was performed after the study as a whole failed to produce positive results. (*Id.* ¶¶ 39-41.) Even if one were to assume that Defendants intended to analyze the AD8 0-1 and AD8 0-2 subgroups before they started the Madison Memory Study – which they did not – none of the results for these two subgroups would be statistically significant after application of a proper statistical correction. (*Id.*) [redacted]. (*Id.* ¶ 42.)

Finally, Plaintiffs' expert, Dr. Sano, contends that the purportedly statistically significant results Defendants report for the AD8 0-1 and 0-2 subgroups are not clinically meaningful, as they do not reflect improvement in memory. (*Id.* ¶ 43-45.) Given the lack of statistically significant and clinically meaningful results, Plaintiffs' experts opine, and Defendants' experts dispute, that the Madison Memory Study does not show that Prevagen improves memory or cognition in humans. (*Id.* ¶ 46.) Resolution of this clash of opinions is predicated on material facts that would undoubtedly "affect the outcome of the suit under the governing law." *ABC v. Goodfriend*, No. 19-Civ-7136 (LLS), 2021 U.S. Dist. LEXIS 166018, at *6 (S.D.N.Y. Sept. 1, 2021) (internal quotation marks omitted). The veracity of these expert opinions is for the jury to decide.

IV. GENUINE ISSUES OF MATERIAL FACT EXIST AS TO DEFENDANTS' OTHER PURPORTED SUBSTANTIATION MATERIALS

A. Genuine Issues of Material Fact as to Animal and *In Vitro* Studies

The parties' experts also offer conflicting opinions on what, if any, conclusions can be drawn from Defendants' animal and *in vitro* research as that research applies to humans. (Pls.' SOF ¶ 47-50.) While Dr. Sano believes that testing on humans is necessary to substantiate Defendants' memory and cognitive improvement claims, Defendants' experts maintain that *in vitro* and animal studies indicate that Prevagen's active ingredient, apoaequorin, provides cognitive benefits. (Defs.' SOF ¶ 84, 86, 88; Pls.' SOF ¶ 47-50.) Defendants' experts assume that these animal and *in vitro* studies have scientific merit and are applicable to humans even though the FTC Guidance cautions that such studies are likely inadequate unless human research is not feasible or such studies are widely accepted in the scientific community as acceptable substitutes for human research, which according to Dr. Sano, they are not. (*See* Graham Decl. Ex. F, FTC Guidance at QUI-FTCNY-00189213-14; *see also FTC v. SlimAmerica, Inc.*, 77 F. Supp. 2d 1263, 1274 (S.D. Fla. 1999) (noting animal and *in vitro* studies "cannot be characterized as serious scientific research" without medical proof that effects would be the same in humans, and thus, did not constitute competent and reliable scientific evidence); *Western Sugar Coop. v. Archer-Daniels-Midland Co.*, No. 2:11-cv-3473-CBM-(PJWX) (C.D. Cal Oct. 23, 2015) (excluding opinions of Defendants' expert, Dr. David Katz, because "studies conducted on laboratory rats are not relevant or reliable under Federal Rule of Evidence 702" without a demonstration of "why the results of those studies should be extrapolated to humans in this case").)

Even assuming the *in vitro*, dog, and rat studies could add up to substantiation for a health claim about efficacy in humans, the studies on which Defendants rely, taken as a whole,

do not substantiate – but rather refute – Defendants' advertising claims. For example, Defendants commissioned a pepsin digestion experiment that demonstrated that apoaequorin is rapidly digested in laboratory conditions that simulate the stomach environment and, thus, would not enter the bloodstream intact to have a therapeutic effect. (Plaintiffs' Response to Defendants' Rule 56.1 Statement ("Pls.' Resp. Defs.' SOF") ¶ 84.) Defendants also commissioned a rat study in which orally administered apoaequorin was not shown to have any protective effect on the rat brains. (Pls.' Resp. Defs.' SOF ¶¶ 84-85.) And Defendants conducted a canine study on orally administered apoaequorin that provided no evidence that it could cross either the gastrointestinal tract or the blood-brain barrier. (Pls.' Resp. Defs.' SOF ¶¶ 84, 86-88.) This evidence supports the conclusion that apoaequorin, administered orally (as Prevagen is), cannot survive digestion intact to have any therapeutic effect. (Pls.' Resp. Defs.' SOF ¶¶ 84-88.)

B. Genuine Issues of Material Fact as to Open Label Research

Dr. Sano opines, and Defendants dispute, that open-label research that lacks a placebo-control and uses only self-reported outcome measures does not constitute competent and reliable scientific evidence to support the Challenged Claims. (Pls.' SOF ¶ 51-53; Defs.' SOF ¶¶ 89-93.) According to Dr. Sano, the Sunsho Pharmaceutical Study suffered from significant methodological flaws in addition to lacking a placebo control and blinding. (Pls.' SOF ¶ 52.) The study also contained no reference to a reliable method for measuring cognitive function and reported serious compliance issues, stating, for example, that only 5 of the 15 subjects took Prevagen every day, as directed. (*Id.*) Defendants' experts conclude that the Sunsho Pharmaceutical Trial reported that "the effect of 'Prevagen' can be considered to be favorable from the viewpoint of its use as a brain supplement." (*Id*. at 53.) This battle of the experts cannot be resolved on a motion for summary judgment.

C. Genuine Issues of Material Fact as to Vitamin D Scientific Literature

Although Defendants added Vitamin D to Prevagen's formula in 2016, approximately nine years after they first sold Prevagen, they have not conducted any testing on the Prevagen formula containing apoaequorin and Vitamin D in the intervening six years. All of Defendants' research is on the apoaequorin ingredient alone. While Defendants maintain that scientific literature supports a relationship between Vitamin D and improved cognitive function, the only basis for this assertion consists of the disputed opinions of Mindy Kurzer, Ph.D., a professor of nutrition who is unqualified to testify competently about the purported cognitive benefits of Vitamin D supplementation under Fed. R. Evid. 702 and *Daubert* and whose testimony on this topic should be excluded.[9] (Defs.' SOF ¶¶ 116-120.) Plaintiffs' expert, Dr. Sano, disagrees with Dr. Kurzer's unfounded conclusions and opines that there is no evidence to conclude that oral administration of Vitamin D, either alone or in combination with apoaequorin, improves memory or provides any other cognitive benefit in the general population. (Pls.' SOF ¶¶ 54-56; Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 22, 114-120, 125.)

[9] Dr. Kurzer has no experience in clinical research involving interventions to treat persons with memory loss or cognitive impairment. (Soberats Decl. Ex. I, Kurzer Tr. at 34:9-36:18.) She is not a member of any academic journals or professional organizations in these areas. (*Id.* at 36:19-37:15.) She is not a clinician, has never evaluated anyone's cognitive function, and has never used the memory assessments employed by Defendants. (*Id*. at 37:16-39:12.); *see, e.g.*, *Daubert*, 509 U.S. at 597. Dr. Kurzer simply has no adequate qualifications to offer competent testimony on memory and cognitive function, or the purported cognitive benefits of Vitamin D supplementation. It is well established that a witness may not offer expert testimony on subjects in which she lacks expertise. Fed. R. Evid. 702. Therefore, Plaintiffs intend to seek leave to move to exclude her testimony.

V. GENUINE ISSUES OF MATERIAL FACT EXIST REGARDING THE USE AND SUFFICIENCY OF THE DISCLAIMER MANDATED BY THE SETTLEMENT IN *COLLINS V. QUINCY BIOSCIENCE, LLC*

Defendants argue that, because they no longer disseminate the specific ads attached as exhibits to the Complaint, and allegedly have incorporated into their current advertising the qualifying language required by the settlement agreement in the matter of *Collins v. Quincy Bioscience, LLC*, they are no longer making the Challenged Claims in violation of the FTC Act and parallel New York law. Defendants' argument fails for multiple reasons. First, on the eve of Plaintiffs' deadline to submit the present brief, Defendants produced evidence that they do, in fact, continue to advertise Prevagen without the Collins Qualifier, despite the representations made in support of their present motion. (Defs.' Br. at 15-16, 46.) Second, Plaintiffs note it is undisputed that Defendants' advertisements did not contain this disclaimer at the time this action was commenced in 2017 and did not even agree to add the Collins Qualifier until 2020. Defendants also ignore the fact that the Complaint does not challenge only the advertisements quoted therein or attached thereto. (*See* Compl. ¶¶ 27, 36, 39, 42, 44.) Additionally, Defendants have failed to produce sufficient evidence to allow the Court to find that the Qualifier, as used in the various media employed by Defendants, changes the net impression of Defendants' ads. Despite admittedly marketing Prevagen through a wide variety of media, including television, radio, and the internet, the only advertising containing the Qualifier that Defendants submitted with their motion consisted of a partial sampling of product packaging and labeling. This simply is insufficient to allow the Court to rule that the wide range of Defendants' current advertising is, by virtue of the Qualifier, not deceptive.

In any event, the Qualifier does not cure the deceptive net impression of Defendants' ads, so that Defendants in fact continue to make the deceptive claims challenged in the Complaint. Thus, disputes over whether all of Defendants' advertising contain the Qualifier and the

sufficiency and effect of the Qualifier constitute issues of material fact precluding summary judgment in Defendants' favor. *See FTC v. DIRECTV*, No. 15-cv-01129-HSG, 2016 WL 5339797, at *3 (N.D. Cal. Sept. 23, 2016) (denying defendants' motion for partial summary judgment on grounds there were issues of fact regarding whether disclosures were sufficiently clear and conspicuous and adequately imparted all required information).

A. Defendants Have Failed to Submit Sufficient Evidence to Show That Their Advertising with the Qualifier is Not Deceptive

Defendants argue that because they allegedly have incorporated the Qualifier into their current advertising, they are no longer making the Challenged Claims in violation of the FTC Act and parallel New York law. Defendants, however, have failed to submit sufficient evidence to support their contention that "[t]he current marketing for Prevagen includes one of the Qualifiers, which are prominently displayed." (Defs.' Br. at 38 (citing SOF ¶ 52).) The Court therefore must disregard Defendants' unsupported assertion of fact. *See Holtz v. Rockefeller & Co.*, 258 F.3d 62, 74 (2d Cir. 2001) (unsupported assertions of undisputed facts must be disregarded).

Defendants do not dispute that they have marketed Prevagen through a wide range of media, including television, radio, print, the internet, and social media. (Soberats Decl. Ex. E, Defendants' Responses and Proposed Counter-Findings to Plaintiffs' Proposed Findings of Fact No. 35.) However, the statement of fact that Defendants cite in support of their assertion that "all" current marketing for Prevagen includes the Qualifier relates only to labeling. (*See* SOF ¶ 52 (citing Olson Decl. ¶ 42).) In addition, while Todd Olson states in his declaration that, following the *Collins* settlement, Defendants incorporated the Qualifier into all new Prevagen advertising, he cites no evidence in support of that assertion. (Olson Decl. ¶ 41.) Indeed, the *only* evidence of advertising containing the Qualifier submitted by Defendants in support of their

motion consists of a partial sampling of packaging and labeling: two packages (for their Extra Strength 60 capsule product) and three labels (for their Regular Strength 30 capsule, Extra Strength 60 capsule, and Professional Formula 30 capsule products). (Olson Decl. ¶ 43, Ex. F.) Defendants submitted no television, radio, or internet advertising, and the Court cannot accept their unsupported assertion that these ads contain the Qualifier. As a result, Defendants have not provided the Court with sufficient evidence to find that Defendants' current advertising does not violate the statutes at issue in this case – to the contrary, they have produced evidence suggesting that their current advertising does contain the disclaimers they claim cures their deceptive claims.[10]

B. Defendants Continue to Disseminate Advertising Without the Qualifier

Despite their assertion to the contrary, Defendants have disseminated ads without the Collins Qualifier since the entry of the *Collins* settlement. Defendants have aired two television advertisements without the disclaimer, both featuring testimonialists making claims about

[10] Defendants should be precluded from submitting any evidence of current advertising not produced to Plaintiffs prior to Defendants' summary judgment filing. *See* Fed. R. Civ. P. 37(c) (a party that fails to supplement its discovery responses as required by Fed. R. Civ. P. 26(e) "is not allowed to use that information … to supply evidence on a motion … unless the failure was substantially justified or harmless"). A party's obligation to supplement its discovery responses extends beyond the close of discovery. *See US v. Dish Network, LLC*, No. 09-3073, 2016 WL 29244, at *5-7 (C.D. Ill. Jan. 4, 2016). Plaintiffs, beginning in February 2022, repeatedly asked Defendants to supplement their discovery responses by producing recently disseminated advertising, including television and radio ads. (Soberats Decl. ¶ 17.) On April 7, Defendants produced a single, 45-page pdf document that appeared to comprise labeling, packaging, printed materials, two radio ad transcripts, and two possible screenshots. *(Id.)* After additional correspondence, in which Defendants initially denied having an obligation to update their discovery responses, Defendants produced 36 television and radio ads on the evening of June 14, two nights before Plaintiffs' deadline to oppose Defendants' motion for summary judgment. (*Id.*) Defendants' delay in making their production—almost four months after Plaintiffs' initial request and on the eve of Plaintiffs' filing deadline—is unjustified. Additionally, Plaintiffs would be prejudiced should Defendants be allowed to submit and argue evidence with their reply.

Prevagen's positive effect on their memory and cognition. (Ducklow Decl. ¶¶ 3-4, Attachments 2-3.)[11] In addition, Defendants' website quincybioscience.com features three testimonial videos—in which the featured individuals make similar claims about Prevagen's benefits—that don't contain the Collins Qualifier. (*Id.* ¶¶ 5-6, Attachments 4-6, 8.) The Collins Qualifier is not displayed on any of the pages of the quincybioscience.com website. (*Id.* at Attachment 4.) The only time it appears, along with audio reference to the Madison Memory Study subgroups, is over three minutes into a five-minute video entitled "Watch the Story of Prevagen" also featured on the website. (*Id.* ¶ 6, Attachment 7.) Thus, as a factual matter, Defendants continue to violate the law as alleged in the Complaint.

C. The Collins Qualifier Fails to Cure the Deceptive Net Impression of Defendants' Ads

For any ad containing the Collins Qualifier, the disclaimer fails to alter the deceptive net impression of Defendants' ads and Defendants therefore continue to make the deceptive claims challenged in the Complaint. The presence of a disclaimer does not necessarily mean that an ad is not deceptive. *Removatron Int'l Corp.*, 884 F.2d at 1497 ("Disclaimers . . . are not adequate to avoid liability unless they are sufficiently prominent and unambiguous to change the apparent meaning of the claims and to leave an accurate impression."); *see also FTC v. Cyberspace.com, LLC*, 453 F.3d 1196, 1200-01 (9th Cir. 2006) (rejecting argument that "fine print notices" on the reverse side of deceptive marketing materials precluded liability under the FTC Act); *Indep. Directory Corp. v. FTC*, 188 F.2d 468 (2d Cir. 1951) (upholding FTC determination that

[11] Defendants failed to produce dissemination for these ads, despite the fact that Plaintiffs had requested such information when Plaintiffs first asked Defendants in February 2022 to update their discovery responses in accordance with Fed. R. Civ. P. 26(e). However, each television ad contains a production date (shown at the beginning of each video) that post-dates the *Collins* settlement, (Ducklow Decl. Atts. 2-3), and Defendants represented on June 13 that the ads they would be producing aired after the settlement date. (Soberats Decl. ¶17.)

marketing materials were deceptive despite presence of printed disclosure). The fact finder must determine the net impression conveyed by Defendants' ad, including whether a disclaimer cures deception. *See, e.g.*, *FTC v. Med. Billers Network*, 543 F. Supp. 2d 283, 304 (S.D.N.Y. 2008); *FTC v. Five-Star Auto Club*, 97 F. Supp. 2d 502, 528 (S.D.N.Y. 2000) (considering the representations "'as a whole without emphasizing isolated words or phrases apart from their context'").

The Collins Qualifier fails to alter the deceptive net impression of Defendants' ads because (1) it is insufficiently prominent; and (2) it improperly represents that Defendants' flawed analysis of subgroups from the Madison Memory Study supports the Challenged Claims. The Qualifier is insufficiently prominent to change the net impression of the only advertising materials Defendants submitted in support of their motion: the packaging and labeling of certain Prevagen products. The Qualifier appears in small font on the back of the packages and labels, while the words "Improves Memory" appear in larger font on the front. (Olson Decl. Ex. F.). The front side of the packaging contains the additional representations that Prevagen supports healthy brain function, sharper mind, and clearer thinking. (*Id.* at QUI-FTCNY-00189976 - QUI-FTCNY-00189977.)

The Qualifier in post-settlement television advertising also is insufficiently prominent to alter the net impression. *See Removatron Int'l Corp.*, 884 F.2d at 1497 (disclaimers must be sufficiently prominent and unambiguous to change the apparent meaning of claims). The Qualifier appears only for a relatively short time, in small, relatively faint font, while other background action and commentary regarding Prevagen's benefits take place. In addition, in larger text, the words "Improves Memory" appear onscreen below the word "Prevagen" for the duration of the ad. In one thirty-second ad, the Qualifier appears onscreen for approximately 6

seconds, in small font, underneath a bar chart purportedly showing a beneficial effect of Prevagen over 90 days. (Ducklow Decl., Attachment 12.) While the Qualifier is onscreen, an upwardly moving arrow appears over the chart, undulating images of jellyfish appear in the background, and the announcer states that "in clinical trials, Prevagen has been shown to improve short-term memory." (*Id.*) Similarly, in a television ad featuring a testimonialist identified as "Douglas," the disclaimer appears in small font near the bottom of the screen for approximately 5 of the ad's 30 seconds, while the testimonialist gestures and makes statements about Prevagen's beneficial effects. *(Id*., Attachment 13.) These disclaimers are insufficient. ("A … brief video superscript in a television ad … [is] not likely to be adequate. … [M]arketers should … avoid small type … and … distracting elements that could undercut or contradict the disclosure." (Graham Decl. Ex. F, FTC Guidance at QUI-FTCNY 00189210.)

Even if the Qualifier were prominently displayed in all advertising, it would be incapable of altering the deceptive net impression of Defendants' ads. The Qualifier states that Defendants' claims are based on the results of subgroups of the Madison Memory Study subjects. (Defs.' SOF ¶ 45.) Plaintiffs' experts, however, have opined that Defendants' subgroup analysis was improper and flawed in multiple respects and therefore fails to prove any beneficial effect of Prevagen. (Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 20, 38, 68-73, 104, 123; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 3(c), 7-9; Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 13-14, 54-56, 59-74, 78(c)-(d); Soberats Decl. Ex. D, Wittes Rebuttal Report ¶¶ 1-3, 5-18, 20-27.) Indeed, in the opinion of Plaintiffs' experts, neither the Madison Memory Study as a whole, nor any other purported substantiation, supports the claims that Prevagen improves memory or imparts any other cognitive benefit. (Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 13-125; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 1-22; Soberats Decl. Ex. C, Wittes Aff.

Report ¶¶ 13-78; Soberats Decl. Ex. D, Wittes Rebuttal Report ¶¶ 1-27.) Plaintiffs therefore contend that no disclaimer or qualifying language could cure the deceptive nature of the Challenged Claims.

VI. DEFENDANTS' CLAIMS ARE LIKELY TO MISLEAD CONSUMERS

Defendants argue that they are entitled to summary judgment because Plaintiffs have failed to offer any evidence that consumers were likely to be misled by their advertisements. (Defs.' Br. at 31.) Defendants' argument is fatally flawed, as it ignores longstanding case law providing that false or unsubstantiated claims are deceptive as a matter of law.

Plaintiffs can demonstrate that a claim is "likely to mislead" consumers by showing that (1) the claim is false; (2) the marketer lacked a "reasonable basis"—or adequate substantiation—for making it; or (3) both. *Alcoholism Cure Corp.*, 2011 WL 13137951, at *26. When advertisers lack a reasonable basis for their claims, the claims "are deceptive as a matter of law." *FTC v. Direct Mktg. Concepts, Inc.*, 624 F.3d 1, 8 (1st Cir. 2010); *Thompson Med. Co., Inc.*, 791 F.2d at 193. Plaintiffs need not provide evidence of actual deception to establish the elements of their case. *See Trans World Accounts, Inc. v. FTC*, 594 F.2d 212, 214 (9th Cir. 1979); *FTC v. Commerce Planet, Inc.*, 878 F. Supp. 2d 1048, 1063 (C.D. Cal. 2012), *aff'd in part*, *vacated in part*, *remanded*, 815 F.3d 593 (9th Cir. 2016).

Plaintiffs thus can demonstrate that Defendants' efficacy claims are "likely to mislead" by establishing through the testimony of their expert witnesses the requisite level of substantiation and that Defendants' proffered substantiation is inadequate. *See Braswell*, 2005 WL 4227194, at *10 (looking to "what experts in the relevant area of study would consider to be adequate in determining the amount of and type of evidence that is sufficient" to substantiate claims). Plaintiffs also can prove that Defendants' establishment claims were false, and therefore deceptive, by showing that Prevagen's efficacy was not substantiated by an RCT.

Defendants' argument that they are entitled to summary judgment on this ground thus is without merit.

VII. THE COURT CAN GRANT PLAINTIFFS' REQUEST FOR INJUNCTIVE RELIEF

A. Defendants Are Engaged in Unlawful Conduct

Relying on *U.S. v. W.T. Grant Co*., 345 U.S. 629 (1953), Defendants argue that the Court cannot grant injunctive relief because, in their view, their unlawful conduct has ceased, and Plaintiffs have not demonstrated that the unlawful conduct is likely to recur. (Defs.' Br. at 34, 41.) Defendants also argue that the FTC has not satisfied the standard for injunctive relief under Section 13(b) of the FTC Act. (*Id.* at 37–38.) Defendants misconstrue the standard for granting injunctive relief and Section 13(b) of the FTC Act. In fact, Defendants' unlawful conduct is ongoing. Even so, Defendants' conduct need not be ongoing, or even likely to recur, in order for the NYAG to obtain injunctive relief.

1. Plaintiffs have satisfied the standard for injunctive relief under *W.T. Grant* that the Second Circuit applies

Defendants' reliance on *W.T. Grant Co.* is misplaced. In *W.T. Grant*, the Court made clear that, "[i]n determining whether to impose an injunction where a defendant has ceased the offending conduct, courts may consider 'the bona fides of the defendant's expressed intent to comply' with the law, 'the effectiveness of the discontinuance,' and 'the character of the past violations.'" *E.E.O.C. v. KarenKim, Inc.*, 698 F.3d 92, 100 (2d Cir. 2012) (alteration omitted) (quoting *W.T. Grant*, 345 U.S. at 633). Although the Court suggested that it might have granted injunctive relief, it found that that it was not an abuse of discretion for the district court to deny injunctive relief under the facts of that case.

Here injunctive relief is well-warranted. Not only did Defendants deceptively advertise for years that Prevagen improved memory and cognition, and was clinically shown to do so,

Defendants' unlawful conduct has not, in fact, ceased. Injunctive relief is therefore warranted. *See Am. Freedom Def. Initiative v. Metro. Transp. Auth.*, 815 F.3d 105, 109 (2d Cir. 2016). When the Complaint was filed, Defendants were actively advertising Prevagen and Plaintiffs alleged that such advertising conveyed deceptive health claims for Prevagen. (*See, e.g.*, Compl. ¶¶ 19–27, 36-45.) Defendants still convey the same deceptive representations for Prevagen that were alleged in the Complaint. Although Defendants argue that their unlawful conduct has ceased as a result of adding the Collins Qualifier, this argument fails because, as discussed above, the Collins Qualifier is inadequate to change the deceptive net impression of Defendants' ads. Moreover, despite Defendants' failure to produce complete dissemination information for their current advertising, Plaintiffs have discovered that at least some of Defendants' current advertisements do not contain the Collins Qualifier, as discussed above.

"The relevant question is whether the defendant's conduct has been 'sufficiently altered so as to present a substantially different controversy from the one that existed when suit was filed.'" *Am. Freedom Def. Initiative*, 815 F.3d at 109 (alteration omitted) (quoting *Lamar Advert. of Penn, LLC v. Town of Orchard Park, N.Y.*, 356 F.3d 365, 378 (2d Cir. 2004)). Defendants have not sufficiently altered their conduct because their supposed "change in conduct" (adding the Collins Qualifier to their advertising) "is 'merely superficial or suffers from similar infirmities as it did at the outset.'" *Id.* (alteration omitted) (quoting *Lamar Advert.*, 356 F.3d at 378). As explained *supra*, Defendants' advertising is deceptive even if their advertisements include the Collins Qualifier. With or without the Qualifier, the advertising conveys the same deceptive representations alleged in the Complaint.

Defendants also ignore that, under the New York laws at issue, the NYAG need not establish that the conduct is likely to recur in order to obtain injunctive relief. *See, e.g.*, *People v.*

Applied Card Sys., Inc., 11 N.Y.3d 105, 109 (2008); *People v. Gen. Elec. Co.*, 302 A.D.2d 314, 316 (N.Y. 1st Dep't 2003) ("[e]ven though GE voluntarily ceased its deceptive practices, the IAS court . . . retained the power to grant injunctive relief . . . .") (internal citations omitted). In *State v. Midland Equities*, 117 Misc. 2d 203, 207 (Sup. Ct. N.Y. Cnty. 1982), the court recognized that "[v]oluntary discontinuance of improper or illegal activity is no assurance that such activity will not be resumed" and that "even if the court were to credit respondents' representations with regard to future activity, an order granting injunctive relief would not harm respondents and could be properly granted." *See also People v. Ludwig Baumann & Co.*, 56 Misc. 2d 153, 159 (Sup. Ct. N.Y. Cnty. 1968) (finding that the injunction will serve as a deterrent to the respondents and any others who may be inclined to "prey upon a gullible and unwary public").

Injunctive relief also is necessary because the *Collins* settlement does not cover all of the claims challenged in the instant action. Specifically, the *Collins* settlement requires Defendants to use the Qualifier only when representing that Prevagen: (1) improves memory; (2) improves memory within 90 days or any other period of time; or (3) reduces memory problems associated with aging. (Graham Decl. Ex. HH, Settlement Agreement and Release at 7.) The settlement therefore does not cover the claims challenged by Plaintiffs that Prevagen "provides other cognitive benefits, including, but not limited to, healthy brain function, a sharper mind, and clearer thinking." (Compl. ¶¶ 36, 42, 44.) The settlement also does not cover any of the establishment claims—those alleging that Prevagen's benefits are clinically shown—challenged by Plaintiffs. (*Id.* ¶¶ 39, 42, 44.) While Defendants might argue that they do, or eventually will, use the Qualifier when making *any* claim for Prevagen, the fact remains that they are not legally obligated to do so.

Accordingly, Plaintiffs have established that injunctive relief is not only permissible, but

necessary.

2. The FTC has satisfied the standard for injunctive relief under the FTC Act

Defendants contend that the FTC has not met the standard for injunctive relief under the FTC Act based on the same argument discussed above: Defendants claim that they have ceased their unlawful conduct by including the Collins Qualifier in their advertisements. (*See* Defs.' Br. at 38; *see also id.* at 41.) This argument also fails, because Defendants' unlawful conduct has not ceased.

To the extent Defendants argue that the standard for seeking injunctive under Section 13(b) is different than under *W.T. Grant*, that argument has no legal support. In particular, Defendants' reliance on the Ninth Circuit's decision in *FTC v. Qualcomm Inc.*, 969 F.3d 974 (9th Cir. 2020), is misplaced. In interpreting Section 13(b), the *Qualcomm* court relied on *FTC v. Evans Products Co.*, 775 F.2d 1084 (9th Cir. 1985). But the standard applied in *Evans Products* (and thus *Qualcomm*) is the same standard that the Supreme Court articulated in *W.T. Grant*: the FTC is entitled to an injunction "if the wrongs are ongoing or likely to recur." *Evans Prods.*, 775 F.2d at 1087 (citing *W.T. Grant*, 345 U.S. at 632-33); *see also Qualcomm Inc.*, 969 F.3d at 1005 (quoting *Evans Prods.*, 775 F.2d at 1087). In other words, *Qualcomm* and *Evans Products* demonstrate that the FTC is entitled to an injunction if it satisfies the *W.T. Grant* standard—which it has.

Defendants misinterpret the other case on which they rely, *FTC v. Shire ViroPharma, Inc.*, 917 F.3d 147 (3d Cir. 2019). The holding in that case established a *pleading* standard under Section 13(b) of the FTC Act: "the FTC must *plead* that [the defendant] 'is' violating or 'is about to' violate the law." *Shire*, 917 F.3d at 161 (emphasis added). This pleading standard is not relevant at the summary judgment stage of the litigation. Moreover, the Complaint clearly

alleged that Defendants' unlawful conduct was ongoing, satisfying the *Shire* pleading standard.[12]

With respect to the question at issue here—whether Plaintiffs are entitled to an injunction at this stage in the litigation—*Shire ViroPharma* concluded that the relevant analysis is whether a defendant's conduct is ongoing or likely to recur, which is the same standard from *W.T. Grant*. *See id.* at 158 ("[T]he 'about to violate' and 'likelihood of recurrence' standards coexist. The 'about to violate' pleading requirement—which is applied right out of the gate—is not inconsistent with the likelihood of recurrence standard, which a court uses to determine the FTC's entitlement to an injunction."). Courts in the Second Circuit apply this same *W.T. Grant* standard to determine whether the FTC is entitled to injunctive relief. *See, e.g.*, *FTC v. Shkreli*, No. 20-CV-706, 2022 WL 135026, at *44 (S.D.N.Y. Jan. 14, 2022); *FTC v. Cuban Exch., Inc.*, No. 12-CV-5890, 2014 WL 3756358, at *4 (E.D.N.Y. July 30, 2014); *Med. Billers Network, Inc.*, 543 F. Supp. 2d at 323. Because Defendants' conduct is ongoing, the FTC has met this standard and thus has satisfied the requirement for injunctive relief under the FTC Act.

B. This Is a Proper Case in Which the Court Should Grant Injunctive Relief

Section 13(b) of the FTC Act "provides that '*in proper cases* the [FTC] may seek, and after proper proof, the court may issue, a permanent injunction.'" *FTC v. Moses*, 913 F.3d 297, 309 (2d Cir. 2019) (alteration in original) (emphasis added) (quoting 15 U.S.C. § 53(b)). Defendants mistakenly contend that the phrase "in proper cases" means the FTC may obtain a

[12] The Second Circuit has never adopted *Shire*'s interpretation of Section 13(b) of the FTC Act. Rather, in *S.E.C. v. Commonwealth Chem. Sec., Inc.*, 574 F.2d 90, 99 (2d Cir. 1978), the Second Circuit interpreted similar language in the Securities Act—authorizing injunctive relief where any person "'is engaged or about to engage in any acts or practices' which constitute or will constitute a violation"—as "requir[ing] a finding of 'likelihood' or 'propensity' to engage in future violations."

permanent injunction *only* where it first has sought a preliminary injunction or temporary restraining order. (Defs.' Br. at 39–40 & n.11.)

To begin with, Defendants cite no authority in support of their novel theory and the only two cases they even mention reached the exact *opposite* conclusion. *See FTC v. Hoyal & Assocs., Inc.*, 859 F. App'x 117, 120 (9th Cir. 2021) ("We have long held that the FTC can obtain injunctive relief without initiating administrative proceedings."); *FTC v. Am. Future Sys., Inc.*, No. 20-CV-2266, 2021 WL 3185777, at *1 (E.D. Pa. July 26, 2021) ("Neither *AMG Capital* nor any other case in this Circuit or others requires FTC to seek or obtain a temporary restraining order or preliminary injunction before pursuing permanent injunctive relief under Section 13(b)."). Indeed, every court that has considered this question has rejected Defendants' reading of Section 13(b). For example, in *FTC v. Electronic Payment Solutions of America Inc.*, the court reasoned that "the provision of §13(b) authorizing the FTC to seek a permanent injunction [] operate[s] separately from the provision authorizing the FTC to seek a preliminary injunction while pursuing administrative proceedings." No. 17-CV-2535, 2021 WL 3661138, at *16 (D. Ariz. Aug. 11, 2021) (citing *Evans Prods.*, 775 F.2d at 1086). And in *FTC v. Neora LLC*, the court rejected the argument that, under Section 13(b), "permanent injunctions are wholly unavailable absent a prior administrative proceeding or previously issued preliminary injunction or temporary restraining order," reasoning that this argument was "inconsistent" with Section 13(b)'s "legislative history and relevant precedent." 552 F. Supp. 3d 628, 635-36 (N.D. Tex. 2021); s*ee also FTC v. Noland*, No. 20CV47, 2021 WL 4127292, at *17 (D. Ariz. Sept. 9, 2021) (same); *FTC v. SuperTherm Inc.*, No. 20CV8190, 2021 WL 3419035, at *6 (D. Ariz. Aug. 5, 2021) (same).

AMG Cap. Mgmt., LLC v. FTC, 141 S. Ct. 1341 (2021), further supports the conclusion that Section 13(b) does not require the FTC to seek a temporary restraining order or preliminary injunction in order to seek a permanent injunction. In *AMG*, the Supreme Court explained that Section 13(b) provides the FTC with two options when seeking injunctive relief from a federal court. First, the statute permits the FTC to seek a temporary restraining order or preliminary injunction, while administrative proceedings are ongoing. *Id.* at 1348 (citing 15 U.S.C. § 53(b)). Second, Section 13(b) may "also be read" as permitting the FTC to "('in proper cases') dispense with administrative proceedings to seek . . . an injunction[]." *Id.* (emphasis omitted). Defendants' argument that *Hoyal* renders "Section 13(b)'s 'proper case' proviso completely superfluous" is wrong. (Defs.' Br. at 39.) It overlooks that, during the course of a Section 13(b) case, the FTC must show its entitlement to injunctive relief twice. When the FTC files its complaint, the Commission must have reason to believe that a defendant's unlawful conduct is ongoing or likely to recur, for it to be a "proper case." Later, when the FTC seeks a permanent injunction, it must show that the injunction is necessary, again, because the defendant's unlawful conduct is ongoing or likely to recur. Here, as discussed above, the FTC has made both showings because Defendants' unlawful conduct was ongoing when the Complaint was filed and is *still ongoing*.

In sum, this action is a "proper case" in which this Court can grant the FTC a permanent injunction.

C. The *Collins* Settlement Does Not Bar the Court From Granting Injunctive Relief

Defendants argue that this Court cannot enjoin the dissemination of advertising that includes the Collins Qualifier because: 1) they "should" not be held liable for complying with a settlement that a Florida district court found to be "fair, reasonable, and adequate"; 2) Plaintiffs

did not object to the *Collins* settlement; 3) advertising with the Collins Qualifier is not deceptive; and 4) it would be "unfair to permit Plaintiffs to assert a new theory of liability." (Defs.' Br. at 41–43.)

Defendants' arguments are incorrect. The main case on which Defendants rely, *California v. IntelliGender, LLC*, 771 F.3d 1169 (9th Cir. 2014), explains why a prior private class action settlement cannot bar a public enforcement action. In that decision, the Ninth Circuit reasoned that a private class action settlement, "though approved by the district court," does not bar a public enforcement action by state or federal government, "even though many of the same claims are included in both actions," because the enforcement action "implicates the public's interest as well as private interests, and therefore the remedial provisions sweep much more broadly." *Id.* at 1173, 1177-78 (discussing "the well-established general principle that the government is not bound by private litigation when the government's action seeks to enforce a federal statute that implicates both public and private interests"). Here, the public enforcement action involves claims under the FTC Act and New York law that implicate the public's interest, and that private class action plaintiffs cannot bring.

In *IntelliGender*, the Ninth Circuit also explained that a public enforcement action is not barred because the government declined to object to the proposed settlement after receiving notice of it. *Id.* at 1178. The statute that requires that the government be notified of class action settlements, "by its own terms, does not 'impose any obligations, duties, or responsibilities upon, Federal or State officials.'" *Id.* (quoting 28 U.S.C. § 1715(f)). Moreover, "state enforcement actions serve other interests such as protecting citizens from future harm, and these interests might not be served by intervention in ongoing settlement proceedings." *Id.* at 1173. Thus, the fact that Plaintiffs did not object to the *Collins* settlement is not a basis for barring this action or

not granting injunctive relief here. *See id.* ("Nothing in [the] notification requirements could be read to interfere with the power of states or the federal government to bring enforcement actions.").

As for Defendants' argument that their advertising is not deceptive because of the Collins Qualifier, that argument has no merit for reasons explained *supra*. Plaintiffs are not asserting a "new" theory of liability. Rather, Plaintiffs have consistently maintained that Defendants' advertising has been and is deceptive—and thus unlawful—for the same reason all along. Whether or not the Collins Qualifier is included, the advertising's net impression conveys the same deceptive representations regarding Prevagen's supposed health benefits that were alleged in the Complaint.[13]

Defendants' claims of prejudice distort the record in this case. The Complaint was filed prior to the *Collins* settlement and of course does not discuss the Qualifier that resulted from that settlement. Following the *Collins* settlement, Plaintiffs' informed Defendants that their ongoing advertisements were deceptive notwithstanding these disclaimers, and Plaintiffs produced television ads with the Collins Qualifier to Defendants on September 8, 2021. Plaintiffs also alerted Defendants that they had not "produced every piece of advertising or marketing disseminated after the entry of [the *Collins* settlement]." Graham Decl. Ex. NN, Pls.' Resps. &

[13] The cases on which Defendants rely are readily distinguishable because the plaintiffs in those cases were trying to raise completely new legal theories that were available at the outset of those actions. *See Lyman v. CSX Transp., Inc.*, 364 F. App'x 699, 701 (2d Cir. 2010) (rejecting new negligence theory based on different facts that could have been alleged in complaint but were raised for first time in summary judgment opposition); *Busher v. Barry*, No. 14-CV-4322, 2019 WL 6895281, at *15 (S.D.N.Y. Dec. 18, 2019) (rejecting new legal theory attempting to revive time-barred claim that the court had rejected multiple times, months prior); *Roberts v. Ground Handling, Inc.*, No. 04-CV-4955, 2007 WL 2753862, at *3 (S.D.N.Y. Sept. 20, 2007) (rejecting new damages theory raised at trial that was not raised during discovery, any motion paper, or any court conference, but could have been raised earlier).

Reply Counter-Findings to Defs.' Prop. Findings of Fact at ¶ 117. This failure is important because, as noted above, it appears that Defendants have *not* included the Collins Qualifier in *every* current advertisement, despite their claims to the contrary.

Accordingly, the *Collins* settlement does not prevent this Court from granting Plaintiffs' requested relief.

VIII. THE NYAG'S CLAIMS ARE NOT PREEMPTED

Defendants have waived any contention that the NYAG's claims are preempted. Defendants raise preemption for the first time in their motion for summary judgment, without citing anything in the factual record or any other reason why this affirmative defense was not raised until five years after moving to dismiss this case and nearly three years after Defendants' answers were filed. This Court has previously recognized that preemption should be raised as an affirmative defense because "[p]reemption is a defense in the nature of avoidance which falls within the realm of Rule 8(c) [of the Federal Rules of Civil Procedure]." *Heller v. Delta Air Lines, Inc.*, No. 922-cv-1937, 1993 WL 330093, at *3 (S.D.N.Y. Aug. 25, 1993). "[O]ne of the main reasons for the rule stated in Fed. R. Civ. P. 8(c) is to avoid surprise to the plaintiff." *United States v. Continental Ill. Nat'l Bank & Trust Co.*, 889 F.2d 1248, 1255 (2d Cir. 1989). It is indeed a surprise that Defendants – who unsuccessfully argued five years ago that the FDA has primary jurisdiction over the NYAG's claims in their motions to dismiss – now assert a preemption defense based on similar principles.

In any event, Defendants' contention that New York's state law claims are preempted is without basis. First, Defendants misconstrue the nature of New York's claims here. The NYAG is not seeking to impose labeling requirements that are different from those imposed under federal law. The NYAG is seeking to have this Court preclude Defendants from making misleading claims – not to force Defendants to make affirmative labeling statements. Second,

Defendants ignore the fact that New York's claims for deceptive advertising are not limited to claims on Defendants' labeling but include misrepresentations on their websites, infomercials, television advertisements, on radio and social media, and in newspapers and magazines. (*See* Compl. ¶¶ 27, 42, 44.) But even more fundamentally, Defendants mischaracterize the applicable federal law. The Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"), as amended by DSHEA, does not preempt state law claims for deceptive advertising.

Deceptive advertising is subject to consumer protection enforcement by the NYAG and the FTC, overlapping with FDA enforcement under DSHEA and FDCA. *See Jovel v. I-Health, Inc.*, No. 12-cv-5614, 2013 WL 5437065, at *5 (E.D.N.Y. Sept. 27, 2013) (noting that although allegedly deceptive statements are part of a dietary supplement's labeling "and may touch on an area regulated by the FDA, consumer protection claims founded on their falsity are not preempted"). The FDA focuses on safety, quality, and labeling, and explicitly defers to the FTC on general regulation of "advertising, including infomercials, for dietary supplements." *See* FDA, *Questions & Answers on Dietary Supplements*, *available at* https://www.fda.gov/food/information-consumers-using-dietary-supplements/questions-and-answers-dietary-supplements (visited June 14, 2022).

The FDCA is "directed to protecting the public by ensuring that drugs sold in the marketplace are safe, effective and not misbranded" while misrepresentations in advertising are "traditional claims of consumer misrepresentation" that are the focus of state consumer protection laws. *Hughes v. Ester C Co.*, 99 F. Supp. 3d 278, 287 (E.D.N.Y. Mar. 27, 2015). Here, as in *Hughes*, the NYAG's claims "do not require reference to FDA definitions, and the misleading nature of the statement[s] can be verified without relying on any special expertise of the FDA." *Id.* (quoting *Jovel*, 2013 WL 5437065, at *5); *see also Jovel*, 2013 WL 5437065, at

*6 ("The FDCA and the state law consumer protection statutes serve complementary, though somewhat overlapping, roles.") (internal quotation marks and citations omitted). Thus, the federal statute applicable in this case – which is directed to false and misleading advertising claims – is the FTC Act, not the FDCA and DSHEA. The FTC Act, which runs in parallel to the state law claims asserted here, does not preempt those claims (nor do Defendants argue that it does).

Moreover, the claims for deceptive practices and false advertising under New York's General Business Law §§ 349[14] and 350 as well as New York Executive Law § 63(12)[15] are based on the marketing, distribution, and sale of Prevagen products in the State of New York, and thus fall within areas traditionally governed by the states' police powers. In such areas, there is a presumption against preemption. *See Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)); *U.S. Smokeless Tobacco Mfg. Co. LLC v. City of New York*, 708 F.3d 428, 432 (2d Cir. 2013); *see also Jovel*, 2013 WL 5437065, at *5 (citing cases) ("In fields traditionally occupied by the states, such as health and safety regulation, there is a strong presumption against federal preemption"). "[P]reemption is an affirmative

[14] Contrary to Defendants' assertion (Defs.' Br. at 17), the NYAG need not establish that it (or anyone) suffered injury as a result of Defendants' deceptive acts and practices in order to obtain relief under Section 349. *Goshen v. Mutual Life Ins. Co. of New York*, 98 N.Y.2d 314, 324 (2002); *People v. Applied Card Sys., Inc.*, 27 A.D.3d 104, 107 (N.Y. 3d Dep't 2005).

[15] Contrary to Defendants' assertion (Defs.' Br. at 17), Executive Law § 63(12) does indeed create an independent cause of action for repeated fraudulent or illegal acts. *See, e.g.*, *People v. Trump Entrepreneur Initiative LLC*, 137 A.D.3d 409, 418 (N.Y. 1st Dep't 2016). Defendants do not advocate summary judgment on the NYAG's Section 63(12) claim (Count III of the Complaint) on account of this argument. Indeed, Defendants previously raised, and dropped, this argument in connection with their Motion to Dismiss. (*Compare* Mem. of Law in Support of Defs.' Mot. to Dismiss (filed Apr. 6, 2017) [Dkt. No. 34] at 21-22 *with* Supp. Mem. of Law in Further Support of Defs.' Mot. to Dismiss (filed June 17, 2019) [Dkt. No. 63] at 9-10.)

defense and the burden of proof lies with the party propounding it." *Izquierdo v. Mondelez Int'l, Inc.*, No. 16-cv-04697, 2016 WL 6459832, at *4 (S.D.N.Y. Oct. 26, 2016).

Courts have also declined to find preemption under the FDCA when a claim could have arisen under state law separate and apart from federal law. *See, e.g.*, *Lara v. Cool Clouds Distrib.*, No. 20-cv-8030, 2021 WL 613842, at *10 (D.N.J. Feb. 16, 2021) (finding no preemption where, even without the FDCA, plaintiff's claims could have arisen from traditional state-law duties to provide adequate warnings about the dangers those products present); *see also Morelli v. Weider Nutrition Group*, 275 A.D.2d 607, 607-08 (N.Y. Sup. Ct. 1st Dep't 2000) (in declining to find preemption over claims that defendant misrepresented nutrition content claims, noting "[w]e perceive no reason to suppose that, in committing the power to enforce the [federal Nutrition Labeling and Education Act], Congress intended to limit a State's otherwise undoubted power to afford consumers within its borders a statutory remedy for injuries caused by knowingly deceptive and misleading business practices . . . ."). In *Elkind v. Revlon Consumer Prods. Corp.*, the court similarly encountered allegations of deceptive advertising on the label of products regulated under the FDCA. No. 14-cv-2484, 2015 WL 2344134 (E.D.N.Y. May 14, 2015). The court concluded that these claims were not preempted because "[t]he FDCA does not endeavor to regulate – and therefore does not purport to pre-empt – whether certain phrases on the branding of non-prescription drugs are misleading." *Id.* at *7. Here, the NYAG's claims are grounded in traditional state-law requirements regarding deceptive business practices, fraud and illegality – requirements that exist separate and apart from the FDCA and DSHEA – and thus are not preempted.

The cases cited by Defendants in support of their belated preemption argument actually refute the concept of preemption in the present context or are otherwise distinguishable. For

example, the court in *Pepsico* (cited in Defs.' Br. at 44) made clear that state law claims could survive a preemption argument "where they are premised on misrepresentations concerning subject matter that the FDA has not endeavored to regulate," e.g., "labeling misrepresentations concerning purified water's ability to clear up the drinker's acne or increase the drinker's intelligence." *In re Pepsico, Inc.*, 588 F. Supp. 2d 527, 538 n.10 (S.D.N.Y. Dec. 8, 2008). In another example cited by Defendants (Defs.' Br. at 44), the court found preemption in a challenge to claims that a mouthwash "Restores Enamel" because the FDA had issued a monograph directly relating to that claim. *Bowling v. Johnson & Johnson*, 65 F. Supp. 3d 371, 2014 WL 5643955, at *3 (S.D.N.Y. Nov. 4, 2014). (*See also* Defs.' Br. at 44-45 (citing *Izquierdo*, 2016 WL 645982, at *4 (finding that plaintiffs' state law claims under GBL § 349 were not preempted by the FDCA); *Bimont v. Unilever U.S., Inc.*, No. 14-cv-7749, 2015 WL 5256988, at *7-*8 (S.D.N.Y. Sept. 9, 2015) (noting that Congress specifically invited the FDA to address "slack-fill" representations on labels); *Greenberg v. Target Corp.*, 402 F. Supp. 3d 836, 841 (N.D. Cal. 2019) (noting that false and misleading claims about the effect of a dietary supplement ingredient would not be preempted by the FDCA) (citation omitted); *Mills v. Giant of Md., LLC*, 441 F. Supp. 2d 104, 106-07 (D.D.C. 2006) (plaintiff seeking to impose an affirmative warning requirement on milk labels where milk labels are subject to "standard of identity" regulations).)

Defendants' argument that the "safe harbor" provisions in New York General Business Law §§ 349 and 350 protect it from suit fails for the same reasons. Those provisions, which provide for a "complete defense" if the practices are permitted by federal law, do not apply where, as here, the practices are *prohibited* by federal law – i.e., the FTC Act. N.Y. Gen. Bus. Law §§ 349(d), 350-d. As discussed above, there are numerous disputes of fact with respect to

the FTC's claims that, if resolved in Plaintiffs' favor, will result in a determination that Defendants' actions at issue here are in violation of federal law. The General Business Law safe harbor provisions would not, therefore, apply.

The "safe harbor" cases cited by Defendants do not suggest otherwise. As noted above, in *Izquierdo*, the court concluded that the plaintiffs' state law claims under New York General Business Law § 349 were *not* preempted by the FDCA and went on to reject the plaintiffs' Section 349 claims because the plaintiff failed to allege injury. 2016 WL 645982, at *4, *7.[16] In *Manchanda v. Educ. Credit Mgmt. Corp.*, No. 19-cv-5121, 2022 WL 137885, at *2-*4 (S.D.N.Y. Jan. 14, 2022), the court found debt collection costs to be covered by the New York General Business Law § 349(d) safe harbor if within federal regulatory limits, but separately addressed deceptive acts and practices claims under Section 349 on their merits. And in *Colella v. Atkins Nutritionals, Inc.*, the court permitted claims to go forward, and did not consider them preempted, where the claims were outside the scope of the federal regulation and the complaint "plausibly alleged that scientific evidence contradicted the defendants' claims." 348 F. Supp. 3d 120, 138 (E.D.N.Y. Dec. 7, 2018). It was only the claims regarding "Net Carbs" – a term that was specifically the subject of FDA guidance and warning letters under the FDCA – that were considered preempted and also subject to the New York General Business Law safe harbor provisions. *Id.* at 134-36 & n.6.

IX. THE NYAG'S CLAIMS FOR RESTITUTION ARE NOT PRECLUDED

Finally, the NYAG's claims for restitution are not barred by the class action settlement in *Collins v. Quincy Bioscience, LLC*. The settlement class in that matter does not include

[16] Unlike the NYAG, only private plaintiffs are required to show injury under Section 349. *See Goshen*, 98 N.Y.2d at 324 (citing N.Y. Gen. Bus. Law § 349(h), the section creating a private right of action).

consumers who were harmed by Defendants' deceptive acts and practices from July 22, 2020 to today, and thus the NYAG is not precluded from obtaining relief for them. (*See* Graham Decl. Ex. JJ, *Collins* Final Order & Judgment (Nov. 18, 2020) at 4 (defining settlement class as limited to individuals who purchased Prevagen products from January 1, 2007 through the date of Preliminary Approval); Graham Decl. Ex. II, *Collins* Order Granting Pls' Am. Unopposed Mot. for Preliminary Approval of Class Action Settlement & Certification of the Settlement Class (July 21, 2020).) In *People v. Applied Card Sys., Inc.*, the New York Court of Appeals made clear that a class action settlement does not preclude the NYAG from seeking restitution for those not bound by the settlement. 11 N.Y.3d 105, 125 (2008). Defendants' arguments relate to individuals covered by the settlement class and are therefore irrelevant to the relief the NYAG seeks.

X. CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that Defendants' motion for summary judgment be denied.

Respectfully submitted,

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